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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/732,721	12/10/2003	Alan L. Kriz	38-15(52826)B	9354

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EXAMINER	
KOROMA, BARBA M	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 11/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/732,721	KRIZ ET AL.	
	Examiner	Art Unit	
	Barba M. Koroma	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 September 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-14 and 16-18* is/are rejected.

7)☒ Claim(s) *2 and 15* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/1/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-16 and 18 in the paper filed on September 16, 2004 is acknowledged. Upon further consideration, it was determined that it would not be a burden to further examine claim 17, and the restriction requirement has been withdrawn. Claims 1-18 have been examined in this Office action.

Priority

2. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 USC 119/120 as follows: it is noted that this application appears to claim subject matter disclosed in prior provisional application 60/434242 filed on 12/18/2002. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or the application data sheet (37CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 USC 119(e) or 120. See 36 CFR 1.78(a). *Correction is requested.*

Specification

3. The disclosure is objected to because of the following informalities: The word --"in"-- preceding the word --contained-- in line 1, page 1, of the specification is incorrectly used. Appropriate correction is required.

4. Two tables carrying different sets of data on page 26 are labeled "Table 1". Correction is required. New matter must be avoided.

Claim Objections

5. Claims 2 and 15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections – 35 USC 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "plant physiological benefit" is unclear. It is not clear what is encompassed by the recitation, for what may be considered a benefit to one may not be considered a benefit to another. The metes and bounds of the claim are unclear.

7. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

regards as the invention. Claim 6 recites "RNA imparting gene suppression." It is not clear whether the recitation is referring to one, several, or all genes of the plant.

8. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation "if" in line 1 renders the claim indefinite. It is unclear whether a transgenic plant that does not carry the heterologous DNA is encompassed. Correction is requested.

9. Claims 11, 12, and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear whether the seed referred to in claims 11-13 contain the exogenous DNA construct. It is suggested that the claims be amended to read as follows: --wherein said seed contain the exogenous DNA construct-- Correction is requested.

10. Claims 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 18 recites "substantially purified". It is unclear when DNA is considered purified or partly purified, as opposed to substantially purified.

11. Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter

which applicant regards as the invention. The recitation "emb5" in claims 1 and 17 render the claims indefinite. The name "emb5" is arbitrarily assigned, does not clearly identify the promoter, and does not set forth the metes and bounds of the invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 1, 3-14, and 16-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn towards a transgenic plant having in its genome an exogenous DNA construct comprising a promoter derived from the 5' regulatory region of any emb5 gene operably linked to a heterologous DNA; or said plant wherein the promoter comprises from about 100 to about 1650 contiguous nucleotides of DNA, wherein said contiguous nucleotides of DNA have from 85% to 100% sequence identity to about 100 to about 1650 contiguous nucleotides of DNA having the sequence of SEQ ID NO: 1; or seed from said plant; or a DNA construct comprising a promoter derived from any emb5 gene operably linked to a heterologous DNA; or said construct wherein said promoter comprises from about 100 to about 1650 contiguous nucleotides of DNA, wherein said contiguous nucleotides of DNA have from 85% to 100% sequence identity

to about 100 to about 1650 contiguous nucleotides of DNA having the sequence of SEQ ID NO: 1; or a method for providing a transgenic plant which produces RNA of interest during embryo development, comprising introducing said DNA construct into a plant; or any substantially purified DNA having promoter activity in plants wherein said promoter comprises from about 100 to about 1650 contiguous nucleotides of DNA, wherein said contiguous nucleotides of DNA have from 85% to 100% sequence identity to about 100 to about 1650 contiguous nucleotides of DNA having the sequence of SEQ ID NO: 1.

The specification indicates that the promoter of the emb5 gene was isolated from genomic DNA of public maize line Mo17. The nucleotide sequence of the promoter is set forth in SEQ ID NO: 1 (page 24, Example 1). Plant transformation vectors comprising the emb5 promoter of SEQ ID NO: 1 operably linked to either intron 1 of the rice actin1 gene or the maize hsp70 intron, and the coding sequence for GUS, were constructed. The vectors were transformed into maize cells by particle bombardment, and transgenic plants regenerated (pages 24-25, Examples 2-3). GUS activity was assayed in the kernel and embryo at various times of development. GUS expression was detected in transgenic embryos at various times depending on the construct, starting at 16 DAP (pages 25-27, Example 4). The specification also indicates that the emb5 promoter is abscisic acid-inducible and emb5 transcripts are not found in seedlings (page 8, lines 10-16). SEQ ID NO: 1 consists of 1658 nucleotides, and transcription starts at nucleotide 1553 (page 8, lines 24-26).

However, the specification does not describe any emb5 promoter, or promoters having from about 100 to about 1650 contiguous nucleotides of DNA, wherein said contiguous nucleotides of DNA have from 85% to 100% sequence identity to about 100

to about 1650 contiguous nucleotides of DNA having the sequence of SEQ ID NO: 1, other than SEQ ID NO: 1. The specification does not describe how the sequence of SEQ ID NO: 1 can be changed without altering its abscisic acid-inducible, embryo-specific transcriptional activity. The specification does not describe the regions of SEQ ID NO: 1 that are essential to its activity, for example regions that confer the abscisic acid-inducibility and embryo-specificity, and which therefore must be present in the promoters encompassed by the claims. The specification indicates the locations of the CAAT and TATA boxes of SEQ ID NO: 1 (page 8, lines 26-27). However, these are regions that are present in numerous eukaryotic promoters of unrelated genes and specificities, and therefore do not distinguish the promoters encompassed by the claims from unrelated promoters. The only structure described in the specification that is correlated with the function of having promoter activity that is abscisic acid-inducible and embryo-specific is SEQ ID NO: 1. Further, as the specification indicates that transcription starts at nucleotide 1553 of SEQ ID NO: 1, no promoter is described that has any sequence identity with nucleotides 1554-1658 of SEQ ID NO: 1.

Further, the specification does not describe any other emb5 gene, or the function of maize emb5. In the absence of this information, one skilled in the art is unable to identify other emb5 genes, and corresponding promoters, from maize or any other plant.

Furthermore, claims 3, 16, and 18 indicate that the promoter comprises from about 100 to about 1650 contiguous nucleotides of DNA, wherein said contiguous nucleotides of DNA have from 85% to 100% sequence identity to about 100 to about 1650 contiguous nucleotides of DNA having the sequence of SEQ ID NO: 1. As written, the region of contiguous nucleotides in the DNA, that comprises SEQ ID NO: 1, does not

have to be within SEQ ID NO: 1. The specification does not describe the promoter activity of any such DNA sequence. Given the breadth of the claims encompassing the promoter of any and all emb5 genes of any and all species, and promoters comprising from about 100 to about 1650 contiguous nucleotides of DNA, wherein said contiguous nucleotides of DNA have from 85% to 100% sequence identity to about 100 to about 1650 contiguous nucleotides of DNA having the sequence of SEQ ID NO: 1, and lack of guidance of the specification as discussed above, the specification fails to provide an adequate written description of the multitude of promoters encompassed by the claims.

13. Claims 1, 3-14, and 16-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for 5' regulatory region of maize *emb5* gene exhibiting promoter activity, depicted as SEQ ID No.1, it does not reasonably provide enablement for 5' regulatory region of other *emb5* genes exhibiting promoter activity derived from all plant species. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with these claims.

The claims are broadly drawn towards a transgenic plant having in its genome an exogenous DNA construct comprising a promoter derived from the 5' regulatory region of any emb5 gene operably linked to a heterologous DNA; or said plant wherein the promoter comprises from about 100 to about 1650 contiguous nucleotides of DNA, wherein said contiguous nucleotides of DNA have from 85% to 100% sequence identity to about 100 to about 1650 contiguous nucleotides of DNA having the sequence of SEQ ID NO: 1; or seed from said plant; or a DNA construct comprising a promoter derived

from any emb5 gene operably linked to a heterologous DNA; or said construct wherein said promoter comprises from about 100 to about 1650 contiguous nucleotides of DNA, wherein said contiguous nucleotides of DNA have from 85% to 100% sequence identity to about 100 to about 1650 contiguous nucleotides of DNA having the sequence of SEQ ID NO: 1; or a method for providing a transgenic plant which produces RNA of interest during embryo development, comprising introducing said DNA construct into a plant; or any substantially purified DNA having promoter activity in plants wherein said promoter comprises from about 100 to about 1650 contiguous nucleotides of DNA, wherein said contiguous nucleotides of DNA have from 85% to 100% sequence identity to about 100 to about 1650 contiguous nucleotides of DNA having the sequence of SEQ ID NO: 1.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands,* 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of undue experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The specification indicates that the promoter of the emb5 gene was isolated from genomic DNA of public maize line Mo17. The nucleotide sequence of the promoter is set forth in SEQ ID NO: 1 (page 24, Example 1). Plant transformation vectors

comprising the emb5 promoter of SEQ ID NO: 1 operably linked to either intron 1 of the rice actin1 gene or the maize hsp70 intron, and the coding sequence for GUS, were constructed. The vectors were transformed into maize cells by particle bombardment, and transgenic plants regenerated (pages 24-25, Examples 2-3). GUS activity was assayed in the kernel and embryo at various times of development. GUS expression was detected in transgenic embryos at various times depending on the construct, starting at 16 DAP (pages 25-27, Example 4). The specification also indicates that the emb5 is abscisic acid-inducible and emb5 transcripts are not found in seedlings (page 8, lines 10-16). SEQ ID NO: 1 consists of 1658 nucleotides, and transcription starts at nucleotide 1553 (page 8, lines 24-26).

However, the specification does not teach promoters from any emb5 promoters comprising from about 100 to about 1650 contiguous nucleotides of DNA, wherein said contiguous nucleotides of DNA have from 85% to 100% sequence identity to about 100 to about 1650 contiguous nucleotides of DNA having the sequence of SEQ ID NO: 1, other than the sequence set forth in SEQ ID NO: 1. The specification does not teach what sequences of SEQ ID NO: 1 may be changed, and what to change them to, in order to obtain promoters that are 100-1650 bases long and that have at least 85% identity to any 100-1650 contiguous bases of SEQ ID NO: 1. The specification does not teach any regions of SEQ ID NO: 1 that are essential to its functional activity. Even minor changes to a promoter can alter its transcriptional activity. For example, Kim et al. (Plant Mol. Biol., 1994, Vol. 24, pages 105-117) teach that minor alterations to a promoter sequence altered, or eliminated, its activity (pages 107- 110, 112-113). In the absence of further

guidance, undue experimentation would be required by one skilled in the art to determine the essential regions of SEQ ID NO: 1, and how its sequence can by changed without altering its functional activity.

Further, the specification does not teach other emb5 promoters from maize or any other plant. The prior art is also lacking in examples of emb5 genes and their promoters. The specification does not teach information that would be required to conclusively identity other emb5 genes, such as the function of the product encoded by the maize emb5 gene from which SEQ ID NO: 1 was derived, and this information is lacking in the prior art. In the absence of this information, it is unclear how one skilled in the art would identify whether a promoter is from an emb5 gene. See Genentech, Inc. v. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Furthermore, claims 3, 16 and 18 indicate that the promoter comprises from about 100 to about 1650 contiguous nucleotides of DNA, wherein said contiguous nucleotides of DNA have from 85% to 100% sequence identity to about 100 to about 1650 contiguous nucleotides of DNA having the sequence of SEQ ID NO: 1. As written, the region of contiguous nucleotides in the DNA, that comprises SEQ ID NO: 1, does not have to be within SEQ ID NO: 1. The specification does not teach that DNA sequences flanking SEQ ID NO: 1 have any promoter activity. Undue experimentation would be required for one skilled in the art to make a promoter that has 85-100% identity to a DNA sequence that is not disclosed as having any such activity. Given the breadth of the

claims encompassing the promoter of any and all emb5 genes of any and all species, and promoters comprising from about 100 to about 1650 contiguous nucleotides of DNA, wherein said contiguous nucleotides of DNA have from 85% to 100% sequence identity to about 100 to about 1650 contiguous nucleotides of DNA having the sequence of SEQ ID NO: 1, unpredictability of the art and lack of guidance of the specification, as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

Conclusion

14. Claims 1-18 are deemed free of the prior art given the failure of the prior art to teach or fairly suggest SEQ ID No. 1.

15. Claims 2 and 15 are objected to, and claims 1, 3-14, and 16-18 are rejected.

Contact Information

16. Any inquiry concerning this or earlier communications from the Examiner should be directed to Barba M. Koroma, whose telephone number is 571-272-0899. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at 571-272-0804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

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